DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NeuroChaos Solutions, Inc.
% Ms. Elisa Maldonado-Holmertz
Consultant
Obelix Consulting, LLC
12416 Fairfax Ridge Place
AUSTIN TX 78738

November 19, 2014

Re: K141462
Trade/Device Name: Varia-NCI
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed Doppler imaging system
Regulatory Class: II
Product Code: IYN
Dated: October 16, 2014
Received: October 21, 2014

Dear Ms. Maldonado-Holmertz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No.0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*
k141462

Device Name

Varia-NCI

Indications for Use *(Describe)*

Varia-NCI is a stand-alone software accessory to a Transcranial Doppler Ultrasound device (TCD) that retrieves, analyzes, and displays Cerebral Blood Flow velocity (CBFv) data from a Transcranial Doppler Ultrasound device. Varia-NCI uses CBFv data to measure the variability of a patient's cerebral blood flow velocity.

Varia-NCI is to be used by clinicians managing head trauma in the ICU, Surgical Unit, Emergency Department, and Clinical and Sports Medicine Settings.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 – 510(k) Cover Letter

510(k) Summary

Varia-NCI

1. Submission Sponsor

NeuroChaos Solutions, Inc.
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Phone: 512.426.5772
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2. Submission Correspondent

Obelix Consulting, LLC
12416 Fairfax Ridge Place
Austin, TX 78738
USA
Contact: Elisa Maldonado-Holmertz, Consultant
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Email: elisamh@obelixconsult.com

3. Date Prepared

30 May 2014

4. Device Identification

Trade/Proprietary Name:	NeuroChaos Solutions, System 1.0
Common/Usual Name:	Accessory to Transcranial Doppler
Classification Name:	Ultrasonic pulsed Doppler imaging system
Classification Regulation:	CRF 892.1550
Product Code:	IYN
Device Class:	Class II
Classification Panel:	Radiology

5. Legally Marketed Predicate Device(s)

Compumedics Germany – Doppler-Box X (K051085)

6. Device Description

Varia-NCI accesses data from Compumedics Germany QL 3.0 software. QL 3.0 is a trade mark of PC-based software supplied by Compumedics Germany, GmbH and included with their digital Transcranial Doppler (TCD) Ultrasound device.

7. Indication for Use Statement

Varia-NCI is an accessory to a Transcranial Doppler Ultrasound device (TCD) that collects, analyzes, stores, and displays Cerebral Blood Flow velocity (CBFv) data. Varia-NCI uses CBFv data to measure the variability of a patient's cerebral blood flow velocity.

Varia-NCI is to be used by clinicians managing head trauma in the ICU, Surgical Unit, Emergency Department, and Clinical and Sports Medicine Settings.

8. Substantial Equivalence Discussion

The following table compares the Varia-NCI to the predicate device with respect to indications for use, intended use, and principles of operation for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	NeuroChaos Solutions, Inc.	Compumedics Germany, GmbH
Trade Name	Varia-NCI	Doppler-Box X
510(k) Number	--	K051085
Product Code	IYN	IYN and ITX
Regulation Number	892.1550	892.1550 892.1570
Regulation Name	Ultrasonic pulsed Doppler imaging system	Ultrasonic pulsed Doppler imaging system
Indications for Use	Varia-NCI is a stand-alone software accessory to a Transcranial Doppler Ultrasound device (TCD) that retrieves, analyzes, stores, and displays Cerebral Blood Flow velocity (CBFv) data from a Transcranial Doppler Ultrasound device. Varia-NCI uses CBFv data to measure the variability of a patient's cerebral blood flow velocity. Vari-NCI is to be used by clinicians managing head trauma	The Doppler-Box is a medical ultrasound device for measuring the blood flow velocities in arteries and veins mainly subcutaneously. The 16MHz probe can also be used intraoperative.

Manufacturer	NeuroChaos Solutions, Inc.	Compumedics Germany, GmbH
	in the ICU, Surgical Unit, Emergency Department, and Clinical and Sports Medicine Settings.	
Predicate	Compumedics Germany GmbH Doppler-Box X	Spencer Technologies; TCD 100M, PWD13 TRANSDUCER K002533 CompumedicsDWL Elektronische Systeme GmbH; Multi-Dop X K931801
Significant Differences	Stand-alone software accessory to a Transcranial Doppler	Digital Doppler sonography system. HD resolution in Doppler M-Mode permits more precise insonation. The innovative hardware design with no integrated computer, but with the possibility to connect to all standard Windows©-based computer systems.

9. Non-Clinical Performance Data

A test report was generated consisting of Test Description, Test Date, Tester Name, Test Criteria, Test Setup, Pass Fail Criteria, and Test Data Files. The report indicates that the software passed the test.

The following software testing has been performed to support substantial equivalence:

- System Integration - Multiprocessing testing : Test Passed
- System Integration - Timing and Memory Allocation : Test Passed
- User Interface Module : Test Passed
    - Single Patient Module – Patient information needs to be displayed.
    - User interface needs to display CBFv variability values and chart
    - The system needs to export results in csv format
    - Patient Data testing
        - CBFv exp files were entered into the database
        - Patient name was entered into the database
        - Patient was recalled and verified that the data was the correct file
- Calculation Testing and Display results : Test Passed
    - The variability of CBFv was calculated and displayed as numeric value and as a chart
- Save results Testing : Test Passed
    - Test results were successfully saved using Save button

- System Verification/Validation – Performance Testing : Test Passed
- Labeling - User Manual Verification/Validation : Test Passed
- Manufacturing : Test Passed
    - Verify that all manufacturing documentation is released
    - All software files checked into VNS Software repository
    - Ran through the software build process and built the package on a clean machine with Delphi XE2 installed.
        - Installed libraries as directed in Build Process
        - Installed

          -ExpressQuantumGrid

          -ExpressBars

          -ExpressNavBar

          -DBSAM
- Installed application software
- Run Delphi and Install supplied application libraries Hyperclass, HyperDSP, ECG, and Miracle:
    - Open Menu: File/Open… Name of the libraryD7.dpk
    - Compiled Software
- Reviewed BOM and Software Package

Varia-NCI is not required to conduct sterilization, biocompatibility, or electrical testing as a standalone software accessory.

As part of demonstrating safety and effectiveness, Varia-NCI shows substantial equivalence as an accessory to the predicate device that is subject to this 510(k) submission. Varia-NCI complies with the applicable Software standards.

10. Clinical Performance Data

No clinical testing is required because the device's indication for use does not substantiate the need for clinical data to support equivalency to the predicate device. The predicate device has been on the market for nearly 10 years with proven safety and effectiveness. The non-clinical testing detailed in this submission confirms the safety and effectiveness of the Varia-NCI.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same operational characteristics as the previously cleared predicate device, or the device has the same intended use and different operational characteristics in which substantial equivalency can be demonstrated in the device in comparison to the predicate device. Additionally, the new device does not raise new questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between Varia-NCI and the predicate device does not raise any questions regarding its safety and effectiveness. Varia-NCI, as designed and produced, is determined to be substantially equivalent as an accessory to the referenced predicate device.